In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-65V
(to be published)

HEIDI SHARPE, *as legal representative of her minor child,* L.M.,	*	Chief Special Master Corcoran
	*	
	*	Filed: February 19, 2021
Petitioner,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Curtis Webb, Twin Falls, ID, for Petitioner.

Voris Johnson, U.S. Dep't of Justice, Washington, DC, for Respondent.

RULING ON REMAND GRANTING ENTITLEMENT[1]

Heidi Sharpe, as legal representative of her child, L.M., filed a petition on January 27, 2014, seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Pet. at 1 (ECF No. 1). Among other things, Ms. Sharpe alleged a causation-in-fact claim that the diphtheria-tetanus-acellular pertussis ("DTaP") and other vaccinations administered to L.M. on February 10, 2011, caused L.M. to experience significant aggravation of a preexisting seizure disorder associated in some part with an underlying genetic mutation. Pet. at 2.

[1] This Ruling will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Ruling will be available in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10–34 (2012) (hereinafter "Vaccine Act" or "the Act"). Individual section references hereafter shall refer to § 300aa of the Act.

After a two-day hearing in March 2018, I denied entitlement in November 2018. *Sharpe v. Sec'y of Health & Hum. Servs.*, No. 14-65V, 2018 WL 7625360 (Fed. Cl. Spec. Mstr. Nov. 5, 2018) (ECF No. 102) ("Entitlement Decision"). Although my decision was initially affirmed by the Court of Federal Claims, it has since been vacated and reversed in part by the Federal Circuit. *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072 (Fed. Cir. 2020) (the "Federal Circuit Decision"). In particular, dismissal of Petitioner's Table claim was affirmed, but my rejection of her off-table significant aggravation claim was vacated and remanded for further proceedings.

After remand, on November 16, 2020, I ordered Respondent to show cause why a ruling on entitlement in Petitioner's favor was not appropriate given the findings in the Federal Circuit Decision. *See* Order, dated Nov. 16, 2020 (ECF No. 125). In reaction, on January 8, 2021, Respondent filed a brief maintaining that Petitioner had not met her burden of proving entitlement to compensation in this case even in light of the Federal Circuit's instruction on the proper interpretation of the significant aggravation legal standard, plus the other fact-findings and evidence-weightings the Circuit panel performed. Brief, dated Jan. 8, 2020 (ECF No. 127) ("Resp. Br."). On January 21, 2021, Petitioner opposed Respondent's argument, maintaining that Petitioner had established that the vaccinations that L.M. received in February 2011 were the likely reason for the significant aggravation of her pre-existing seizure disorder, and thus entitlement to compensation should be granted. Brief, dated Jan. 21, 2021 (ECF No. 129) ("Pet.'s Br.").

Based upon evaluation and review of these filings, the Federal Circuit Decision, and my own extensive review of the records filed in this case, I hereby find Petitioner is entitled to an award of damages, for the reasons set forth below.

Brief Procedural History

The November 2018 Entitlement Decision

This ruling incorporates by reference the Entitlement Decision and the Federal Circuit Decision.[3] In summary, I initially determined (after a hearing involving the testimony of four experts) that Petitioner had not satisfied enough of the prongs of an off-Table significant aggravation case (as set forth in *Loving v. Sec'y of Health & Human Servs.,* 86 Fed. Cl. 135, 144 (2009)) to establish that her preexisting seizure disorder, associated with an identified genetic mutation, was likely worsened by receipt of the DTaP vaccine (the vaccine most focused-upon in the case—although not exclusively). Entitlement Decision at *32. That seizure disorder was agreed by the parties to have a relationship to the "DYNC" (as defined in the Entitlement Decision)[4]

[3] Citations to specific pages within these two published decisions will be to the official Westlaw versions, although I will refer to the decisions generally by their defined titles in this Ruling.

[4] *See* Entitlement Decision at *39.

genetic mutation L.M. unquestionably possessed—and it was also agreed that the mutation was predictive and causal of *some* future seizure disorder issues in an infant, although Petitioner maintained that but for vaccination L.M.'s course would have been far less severe.

Based on testimony at the entitlement hearing plus the medical records and numerous items of medical and scientific literature filed in this matter, I found that Ms. Sharpe had at least satisfied *Loving* prongs one, two, and six. Entitlement Decision at *41. There was no dispute that L.M. possessed the DYNC genetic mutation prior to vaccination (*Loving* prong one) but had only displayed some mild initial seizure activity, and the nature and status of her overall seizure disorder post-vaccination was also established in the record (*Loving* prong two). In addition, the record supported Petitioner's claim that the timeframe for onset of her alleged vaccine-caused worsening of the disorder was medically acceptable, assuming the theory itself had been preponderantly established (*Loving* prong six). *Id.* at *10-11, *41.

However, Petitioner's significant aggravation claim still failed, in my initial estimation. Regarding the third *Loving* prong, I found that Ms. Sharpe had not established that L.M.'s post-vaccination course varied enough from what otherwise would be expected for a child possessing the DYNC mutation to be deemed a "significant aggravation" of the otherwise genetically-caused seizure disorder. Petitioner's geneticist, Dr. Richard Boles,[5] did not preponderantly establish through his testimony that the precise location of the mutation on the DYNC gene was predictive of severity/outcome, since other reliable evidence offered in the case demonstrated instances that contradicted his assertions. A case report involving L.M. herself and a comparable child lent support for the contrary conclusion (since *both* featured mutations in the same gene location, and both had experienced comparable seizure courses). Entitlement Decision at *17-18, *36-37.

By contrast, Respondent's pediatric seizure expert, Dr. John Zempel, persuasively demonstrated that L.M.'s course would more likely than not have been the same even if the DTaP vaccine had temporarily triggered some intervening seizure activity. Entitlement Decision at *21-22. Unlike Dr. Boles, Dr. Zempel regularly treated infants with seizure disorders, giving his opinions a heft that Petitioner's expert opinions lacked. He established the low likelihood that

[5] I similarly rejected the opinion offered by Petitioner's other expert, Dr. Robert Shuman, that a brain malformation explained L.M.'s seizure disorder, since his opinion predated discovery of the mutation and was otherwise unpersuasive. Entitlement Decision at *38-39. The core of Dr. Shuman's testimony and opinion arose from his interpretation of L.M.'s various MRIs, which he proposed demonstrated the existence and extent of an underlying encephalopathic condition. *Id.* at *8. Dr. Shuman maintained that the vaccines precipitated her seizures (although he did not maintain that the vaccines *caused* the preexisting abnormalities themselves), and in particular that pertussis toxin-containing vaccines, such as the DTaP vaccine L.M. received, promote seizure activity. *Id.* at *10. However, as I discussed in the Entitlement Decision, Dr. Shuman relied heavily on outdated medical literature involving the DPT vaccine (which the DTaP vaccine supplanted), conflating the two as equally-dangerous even though the DTaP version (which L.M. received) was well-known to be less likely to provoke seizures. *Id.* at *38. And Dr. Shuman also did not persuasively establish that L.M. possessed the proposed brain malformation, or that vaccination exacerbated it. The Federal Circuit did not disturb this component of the Entitlement Decision.

intervening vaccination would push an otherwise genetically-caused seizure disorder onto a more dire course. In so finding, I relied on prior cases (decided by the Court of Federal Claims as well as the Federal Circuit) holding that a showing of expected course/illness trajectory was required when asserting an off-Table significant aggravation claim, since the concept of worsening could not be itself addressed without some consideration of the otherwise-expected course. *Id.* at *35-36. I also noted that L.M.'s mutation was somewhat analogous to the SCN1A mutation, which is also known to be causal of seizure disorders but understood not to be worsened by vaccination (as confirmed in a series of Vaccine Act decisions). *Id.* at *30, *40.

In addition, I determined that Petitioner's *Loving* showing was deficient in two other respects. First, I reasoned that Petitioner had not preponderantly demonstrated that *Loving* prong four (which corresponds to the first prong of the Federal Circuit's non-Table causation test set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (2005)) was satisfied—that the DTaP vaccine "can cause" worsening of a DYNC mutation. Entitlement Decision at *38-39. Petitioner provided little in the way of a persuasive and scientifically-reliable explanation for *how* the DTaP vaccine could provoke worsening of an otherwise-predictable seizure disorder. *Id.* at *40. Dr. Boles instead largely relied on self-reported anecdotal instances of vaccines worsening genetically-caused conditions and the role environmental impacts can play, but he could not back up his contentions with immunologically-based argument establishing the bones of a theory for how vaccination could worsen the condition's course. He particularly struggled to offer reliable scientific or medical proof associating vaccines of any kind with the sparking of a seizure disorder connected to the DYNC mutation or some other comparable genetic mutation. *Id.* at *15. His lack of specific immunologic expertise also was unhelpful to the persuasiveness of his testimony on these matters. And my decision pointed out that the DTaP vaccine is no longer believed to be as associated with provoking of seizures as its predecessor version (the DPT vaccine). *Id.* at *31-32.

Second, I found that the fifth *Loving* prong (comparable to *Althen* prong two)—that the vaccine in question "did cause" worsening of L.M.'s genetically-caused seizure disorder—was not preponderantly established. Entitlement Decision at *40-41. My review of the medical record suggested to me that any post-vaccination fever L.M. had experienced had been transient, and thus had not been demonstrated to possess more than a temporal relationship to any subsequent worsening of her seizure activity. *Id.* at *41. I also noted that the record established that L.M.'s seizure course had likely already begun before vaccination, with evidence of initial seizure activity within the month prior to vaccination (making it difficult to conclude that the vaccine's interposition necessarily was an inflection point in her subsequent downward progression). *Id.* Indeed, I concluded that Dr. Boles placed undue stock in the temporal relationship as proof of vaccine causation, something other Federal Circuit cases warn against. *Id. (*citing *McCarren v. Sec'y of Health & Human Servs.,* 40 Fed. Cl. 142, 147 (1997)).

2020 Federal Circuit Decision

The Circuit overturned my dismissal of the claim—based not only upon its determination that I erroneously applied *Loving*, but also that certain of my underlying fact or credibility determinations were arbitrary and capricious.

With respect to the law, the appellate panel held that *Loving* prong three does *not* require a petitioner to demonstrate an expected outcome, such that her current-post vaccination condition was worse than such expected outcome. Federal Circuit Decision at 1081. The Circuit based this holding on the fact that the Vaccine Act only requires a "comparison of the person's pre-vaccination condition with the person's current, post-vaccination condition." *Id.* (citing 42 U.S.C. § 300aa-33(4)). In so doing, the panel attempted to explain what role remained for consideration of the fact (inherent to any significant aggravation claim) that an injured party's injury was connected to some pre-vaccination condition, allowing that "evidence of other possible sources of injury can be relevant not only to the 'factors unrelated [inquiry], but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question." *Id.* (citing *Stone ex rel. Stone v. Secretary of Health & Human Services*, 676 F.3d 1373 (Fed. Cir. 2012)). But there was a "fine line" between a court properly considering evidence in the record (*Stone,* 676 F.3d at 1380) and improperly placing the burden on the petitioner to prove that her significantly aggravated condition was not caused by her pre-existing condition. *Id.* at 1082. In the Circuit's reasoning, requiring a comparative showing of expected versus actual outcome on this prong crossed that line. [6]

Regarding *Loving* prong four (congruent with *Althen's* "can cause" first prong), the Circuit emphasized that a petitioner may be able to make out a prima facie case that the vaccine could cause the condition at issue *without* eliminating a pre-existing condition as the more likely cause of her significantly aggravated injury. Federal Circuit Decision at 1083. If a petitioner successfully does so, the burden later shifts to Respondent under the "factor unrelated" inquiry to show that the pre-existing condition likely caused the significantly worsened condition. *Id.* (citing *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007). [7]

[6] In so determining, the Circuit panel announced a somewhat novel interpretation of the significant aggravation standard, requiring far less of petitioners in the non-Table context than in the past. And although the panel deemed its construction of this *Loving* prong consistent with its prior decisions, Respondent took issue with that assertion—as reflected in the fact that Respondent moved for *en banc* reconsideration of the Circuit's decision. Fed. Cir. Doc. No. 48. The reconsideration motion argued that the Circuit Decision on this *Loving* prong conflated decisions interpreting the significant aggravation standard applied in the *Table* context (where causation is presumed—and thus claimants are tasked with satisfying a somewhat lower legal standard of evidentiary sufficiency) with non-Table, causation-in-fact claims—and thus effectively endorsed a lowered evidentiary standard for non-Table claims contrary to the Circuit's own prior decisions on this very subject. The motion was rejected without a reasoned decision addressing Respondent's objections.

[7] The Federal Circuit Decision also repeatedly used the term "plausible" to characterize the causation showing a petitioner alleging a non-Table significant aggravation claim must make. *See, e.g.*, Federal Circuit Decision at 1075,

Loving prong five requires a petitioner to show "a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation." *Loving,* 86 Fed. Cl. at 144. The Circuit explained that since a significant aggravation claim, by definition, requires a petitioner to possess some pre-existing condition or injury subject to worsening, the fact that a petitioner suffers from symptoms of her pre-existing injury prior to vaccination should have no negative affect on the petitioner's case. Federal Circuit Decision at 1079-80.

With the foregoing as a framework, the Circuit made some fact findings relevant to the *Loving* prongs I decided. For example, I initially found that preponderant evidence had been offered by Respondent showing not only that the DYNC mutation is *generally* associated with poor outcomes, but also that an individual with the same mutation and location as L.M. had experienced a parallel course—suggesting to me that location was not necessarily determinative of outcome. Entitlement Decision at *42 n.47. I acknowledged that Dr. Boles maintained that L.M.'s mutation was expected to be mild because it was located in the stem/tail region of the gene, and not the motor region, and did offer some reasonable/reliable evidence to support his contention. Entitlement Decision at *12. But I ultimately concluded that Respondent's genetics expert (Dr. Maria Descartes) was more persuasive on this point. *Id* at 39. I also gave some weight to evidence offered relating to the SCN1A mutation, also responsible for seizure disorders but not deemed to be worsened by vaccination. *Id.*

The Circuit, however, found (based upon its own review of the record) that this finding lacked evidentiary support. Rather, the location of L.M.'s mutation, in the stem region as opposed to the motor region, was in the Circuit's view more likely than not associated with non-severe, non-cognitive disorders such as spinal muscular atrophy with lower extremity predominance. Federal Circuit Decision at 1086. As a result, L.M.'s stem-located mutation was not likely the sole, substantial factor causing her severe seizure disorder. *Id.* The Circuit further emphasized that given the complexity of a significant aggravation claim generally, a Vaccine Act petitioner should not be required to *disprove* at the outset that a pre-existing genetic mutation caused her significant aggravation. *Id.* at 1087. Most importantly, the Circuit deemed Dr. Descartes to have conceded outright that vaccination generally could adversely impact a preexisting DYNC mutation. Federal Circuit Decision at 1085.[8] As a result, the third and fourth *Loving* prongs should have been decided

1083, 1085. This interpretation of *Loving* prong four/*Althen* prong three is inconsistent with other, prior Circuit determinations that clearly reject plausibility as inconsistent with preponderance. *See Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof").

[8] The record on this point is less crystal clear than the Federal Circuit Decision suggests. Dr. Descartes only agreed that an *infection*—an active and invasive process substantially more difficult to process than vaccination, even if the two are on the same spectrum—could be something a child with a preexisting genetic disorder might find difficult to cope with biologically. She unquestionably did *not* concede that vaccination was comparable. *Compare* Circuit

for Petitioner, and that my contrary determinations were in error. It remanded the matter for final disposition.

Order to Show Cause and Parties' Respective Positions

Given the above, it seemed likely to me that an entitlement ruling for Petitioner was now not only contemplatable but mandated. However, I determined that I would give each side a chance to propose what was left to decide in the matter that could conceivably result in a second unfavorable entitlement decision, since the scope of the remand remained vague in some respects.

Respondent went first. He acknowledged the factual findings made by the Circuit supportive of entitlement, specifically admitting (while not conceding the persuasiveness of the controlling findings) that I am bound *both* to find that *Loving's* "can cause" fourth prong is effectively satisfied, and also that (had I gone on to apply the burden-shifting analysis after a petitioner meets her prima facie case) Respondent had not preponderantly satisfied the "factor unrelated" defense. Resp. Br. at 2-3. Thus, Respondent seems to accept that my sole remaining task is to evaluate if *Loving* prong five has been met.

In so doing, however, Respondent maintained that the Circuit appeared to embrace an unsound legal standard. Thus, the panel specifically proposed that I determine whether evidence that a vaccine *can cause* an injury (*Loving* prong four), combined with a proximate temporal relationship (*Loving* prong six), can satisfy petitioner's burden of proving a logical sequence of cause and effect showing that the vaccine in fact *did cause* injury (*Loving* prong five). Resp. Br. at 1, *citing* Federal Circuit Decision at 1072 n.5. Respondent argued that this construction of the law was based on dicta rather than existing Federal Circuit precedent, reflected an improper muddling of the otherwise-distinct legal standards separating Table from causation-in-fact claims, and would, if embraced, "negate" a petitioner's obligation to prove with preponderant evidence the "did cause" *Loving* prong. Resp. Br. at 5-6. This was especially so since other Circuit precedent clearly stands for the proposition that a temporal association between vaccine and injury (here, worsening of a preexisting injury) is not enough upon which to prevail. Respondent otherwise took issue with the strength of Petitioner's showing on the fifth *Loving* prong, maintaining that it relied too much on a mere proximate temporal relationship between vaccination and worsening. *Id.* at 3-4.

Petitioner in response has argued that my own Entitlement Decision plus the Federal Circuit Decision have resolved all *Loving* prongs in her favor but the fifth. Pet's Br. at 1-2. Thus, the only question remanded for my consideration is whether the Petitioner demonstrated a logical

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Decision at 1085 *with* Entitlement Decision at *18. Respondent's experts never embraced the contention that vaccination likely worsens preexisting seizure disorders. Tr. at 323-328.

sequence of cause and effect that showed that L.M.'s vaccinations were the reason for the significant aggravation of her preexisting condition. *Id.* at 2. To do so, Petitioner maintains that I should accept the Circuit's formulation of the standard (i.e. that satisfaction of prongs four and six could also meet the fifth, if supplemented with expert support), over Respondent's position that it reflected dicta. *Id.* at 11-12.[9]

To support her contention, Petitioner notes a number of items of evidence or factual determinations. She references the testimony of Dr. Boles as well as her other expert, Dr. Robert Shuman (although his causal opinion arose from contentions about a purported preexisting brain malformation that I did not deem persuasive or reliable—conclusions the Federal Circuit Decision did not overturn or contest). Pet.'s Br. at 4. She also noted the testimony of Dr. Descartes, whom the Circuit found had conceded that a vaccine might promote neurologic deterioration in someone with a preexisting genetic mutation. *Id.* at 5-7. Thus, because of the above, and given that the record establishes that L.M. experienced a seizure within four days of her February 11, 2011 vaccination (a timeframe I unquestionably found to be medically reasonable under Petitioner's causation theory), the "did cause" *Loving* prong was met. *Id.* at 10.

ANALYSIS

The Federal Circuit's Decision unquestionably forecloses further consideration of Respondent's success in establishing alternative cause/factor unrelated based on the DYNC mutation.[10] When a petitioner carries her initial burden to prove causation-in-fact, the burden shifts to the Respondent to show by a preponderance of the evidence that a "factor unrelated" to the vaccine was the "sole and substantial factor in bringing about the injury." *Hammit v. Sec.'y of Health & Human Servs.*, 98 Fed. Cl. 719, 726 (2011), *aff'd, Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373 (Fed. Cir. 2012). In my Entitlement Decision, I found that L.M.'s DYNC gene mutation was the most likely sole, substantial factor in causing L.M.'s seizure disorder (although I did so in the context of evaluating whether Petitioner's prima facie case was met, and

[9] Petitioner also addressed Respondent's assertion that the Circuit's decision created a "new class of 'Table' claims" subject to a reduced evidentiary standard. Pet.'s Br. at 11-12 (citing Resp. Br. at 5). She argued this was incorrect, since the Circuit had noted that the evidence used to satisfy the fourth and sixth *Loving* prongs would still need to be linked to some medical opinion that the vaccine was likely causal of the injured party's worsening. Pet.'s Br. at 12. Petitioner maintained she had done so, since she presented two expert witnesses who testified that the circumstances of L.M.'s injury provided a logical sequence of cause and effect associating L.M.'s 2011 vaccinations with the significant aggravation of her preexisting condition. *Id.* Of course, as I noted in my original decision, Dr. Boles's opinion on this point was itself heavily reliant on the temporal association—meaning that, in my estimation, he did not provide much of an independent basis for finding that the vaccine was likely causal. Dr. Boles did, however, also reference his own anecdotal experience regarding the impact of vaccines on a person like L.M. already challenged by a preexisting mutation-associated seizure disorder.

[10] My initial decision only addressed Respondent's success in meeting this burden-shifting obligation as a footnote, since I had determined that Petitioner's failure to meet all of the *Loving* prongs meant the burden never shifted to Respondent. Entitlement Decision at *36 n.47.

considered the issue specifically under *Loving* prong three). Entitlement Decision at *36. Regardless of whether that analysis was properly conducted, the Circuit has found that the DYNC mutation does not likely explain L.M.'s overall post-vaccination seizure disorder course, and I must proceed from that determination.

Both sides otherwise seem to agree that resolution of the fifth *Loving* prong remains the prime issue to be decided on remand. But they disagree as to the construction of this prong under the circumstances. Contrary to Petitioner (and to the Circuit's reference to the matter—which by its own terms left it as an undecided issue), I do *not* find that a Vaccine Program claimant could prevail on the fifth *Loving* prong simply by relying on her success in establishing the other two prongs and then combining that with an expert opinion, without any consideration by the special master as to the evidentiary value or weight that kind of opinion should receive. Rather, the fifth *Loving* prong, like the other two, requires a *preponderant* showing—and that in turn means that the items of evidence offered to satisfy it must be reliable. Success on two of the prongs in itself does not obviate that requirement.

My conclusion flows from the best understanding of how the "did cause" prong under *Loving* or *Althen* should be applied. As observed in my Entitlement Decision, evidence to establish "a logical sequence of cause and effect" is "usually supported by facts derived from a petitioner's medical records." Entitlement Decision at *24. Certainly the opinions of treaters who have provided medical care to an alleged vaccine-injured person are entitled to weight in the Program, and such an opinion, bulwarked with record evidence that the injured party's experience was consistent with what a vaccine injury is theorized to look like, can be sufficient to meet this *Loving* prong (as well as its counterpart *Althen* prong). But at the same time, a conclusory opinion that a vaccine was likely causal—mainly because (a) the injury post-dated vaccination, and (b) the opining treater/expert cannot identify anything else causal—is not especially persuasive. To allow that sort of opinion alone to satisfy the "did cause" prong, simply because two other prongs had already been met, would be akin to permitting Petitioners to ignore the requirement that they meet *all* prongs with preponderant evidence. *Althen,* 418 F.3d at 1278. It would also run up against the prohibition on granting entitlement simply on the basis of the showing that the injury post-dated vaccination.

It is also, however, the case that *many* kinds of evidence can be offered in support of a Vaccine Injury claim, with no one category "required." *See Capizanno v. Sec'y. of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006). Subsumed within that general proposition is the concept that *any* evidence might be offered to support any particular *Althen* or *Loving* prong (with the obvious proviso that some items of evidence might be less useful in proving one kind of claim element than other categories). Thus, a medical treater's opinion that a vaccine likely caused a person's injury might have some *Althen* prong one bearing (although less so than an expert qualified to opine on causation in a specific case), with the opposite also true (since causation experts are often also asked to review a claimant's medical record in order to give support to the

"did cause" prong). And just as the third *Althen* prong is correctly understood to mix the first two (since a successful claimant must demonstrate that the timing of injury onset as reflected in the medical record coincides with what the causation theory proposes could occur), there is no reason why evidence pertaining to timeframe might also bear on whether the vaccine did cause the injury alleged.

Thus, although the fact of a petitioner's success in establishing prongs four and six of the *Loving* test cannot be leveraged to meet the fifth simply because it is hitched to an expert/treater opinion, the *evidence* that was offered to satisfy those former prongs can unquestionably be applied to the latter. And an expert report, coupled with such other evidence, might be enough to demonstrate the vaccine in question did aggravate a preexisting condition (depending of course on the weight the report receives).

In light of the above, I note the following fact issues, which are either undisputed or have been determined as a result of the Circuit's decision. Neither party disputes L.M. had the DYNC mutation and had begun to have seizures before vaccination, and Petitioner could not persuasively show that L.M. would never have experienced *any* poor outcomes given it. However, it has also been decided by the Circuit that the nature of the mutation in question (given Dr. Boles's assertions about its location) made it unlikely to have a severe outcome consistent with what L.M. has experienced. And it is now determined (based largely on Dr. Descartes' purported concession) that vaccination could worsen an expected seizure course, presumably through neuro-inflammation attributable to fever. Further, the onset/manifestation of L.M.'s worsened course began in a medically-acceptable timeframe when measured from her date of vaccination four days prior.

So—did the DTaP vaccination that L.M. received, and that likely caused her to experience (alone or in concert with the other vaccines she had simultaneously received) a fever, aggravate her DYNC mutation-oriented condition? The evidence Petitioner offered on this point remains quite thin. Dr. Boles was vague in explaining how vaccination worsened L.M.'s condition, beyond reliance on generalities about environmental effects or his own experience with patients that he could not corroborate. He certainly lacked the immunologic expertise to flesh out this aspect of his opinion—and what Petitioner did offer about the DTaP vaccine relied on findings pertinent to its predecessor version (DPT) that no longer hold true for the acellular version. I also observe that Petitioner marshalled no direct treater support for her claim, from medical providers who actually saw L.M. during her initial presentation, relying on the comparatively-weaker evidence from Dr. Boles (who did not himself treat L.M.), although some *later* treaters associated the initial, vaccine-caused fever with her progressive decline.

However, the record establishes that L.M. experienced some transient reaction the evening of February 10, 2011, after administration of several vaccines including DTaP. Entitlement Decision at *41. Several days later, she began experiencing seizure activity that was observed in the contemporaneous medical record. And then as the months progressed, her condition deteriorated. Clearly the significance of Dr. Descartes's "concession" on causation is amplified by

the fact that L.M. in fact experienced a fever after vaccination—and this fever, under Petitioner's now-accepted significant aggravation theory, could worsen seizure activity, as the record reveals occurred to L.M. not long thereafter, and in a timeframe I otherwise deemed medically acceptable. I give far more weight to such contemporaneous record proof than to a conclusory opinion from Dr. Boles on why L.M.'s course worsened.[11]

Thus, even though Petitioner's overall showing on the fifth *Loving* prong was not notably robust, it was preponderant *enough* to meet her burden of proof. As is well understood in the Program, preponderance simply means more than fifty percent—a standard that can be difficult to meet, but one that is far from requiring certainty. *Bunting v. Sec. of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). Indeed, even in a tie, where the evidence is in equipoise, persuasive case law suggests that special masters should find for petitioners. *Contreras v. Sec. of Health & Human Servs.*, 107 Fed. Cl. 280, 292 (Fed. Cl. 2012) (citing *Althen*, 418 F.3d at 1280 (in the system provided for deciding vaccine injury claims, close calls regarding causation are resolved in favor of injured claimants) (internal citations omitted)). Here, such a weakly-preponderant showing has been made. The record evidence about what actually happened to L.M. supports Petitioner's claim just enough for me to conclude that the evidence is at least in equipoise—meaning Petitioner should receive the benefit of the doubt.

The admitted little that is still known about the DYNC mutation and its possible interaction with vaccines is to no small extent another factor favoring Petitioner herein—as a comparison with what is known about the SCN1A mutation reveals. A series of Program decisions involving the SCN1A mutation has put to rest the prior view (for purposes of entitlement) that vaccination could be causal of Dravet syndrome, a seizure disorder much like what L.M. has experienced. Before scientific understanding on the matter had sufficiently advanced, cases involving Dravet syndrome were routinely decided in petitioners' favor—but not after. *See, e.g.*, *Oliver v. Sec'y of Health & Human Servs.*, No. 10-394V, 2017 WL 747846, at *28 n.3 (Fed. Cl. Spec. Mstr. Feb. 1, 2017), (setting forth 15 cases denying compensation for alleged vaccine-caused Dravet syndrome), *mot. for rev. den'd*, 133 Fed. Cl. 341 (2017), *aff'd*, 900 F.3d 1357 (Fed. Cir. 2018); *rehearing en banc den'd*, 911 F.3d 1381 (Fed. Cir. 2019).

Far less is currently understood about the DYNC mutation, making it much harder to say, in the context of this legal proceeding, that preponderantly the mutation is likely to lead to outcomes such as that experienced by L.M. Indeed, as even my Entitlement Decision acknowledged, Petitioner's arguments about outcomes associated with this mutation (when evaluated in light of location of mutation) have reliability. Entitlement Decision at *36. In future

[11] Indeed—were this a case where the petitioner could *not* establish record evidence of a vaccine reaction, and relied solely on the fact that her seizure activity worsened days after vaccination, I would not find this prong satisfied simply on the basis of satisfaction of the other two prongs plus a conclusory expert opinion.

Vaccine Act matters,[12] Respondent may be able to fill in these evidentiary holes, as he did with respect to the SCN1A mutation before, making it easier to conclude defensibly that vaccination could not worsen the DYNC mutation's expected symptomatic course. But for now, the evidence herein is enough to conclude that but for the DTaP vaccine, L.M.'s course would have likely been less severe, and she therefore should receive compensation for her tragic injuries.

Conclusion

Although I have determined that the evidence preponderates in Petitioner's favor on the "did cause" *Loving* prong, reasonable considerations about the interests of justice in Vaccine Program cases *also* support a prompt entitlement decision in Petitioner's favor. This matter is now more than seven years old. Even with my determination, it is likely the case will take significantly more time to resolve damages, given the difficulties inherent in establishing a life care plan for a child with the kind of intractable physiologic injuries L.M. unquestionably experiences. Should further appeals ensue, the case's life will be additionally prolonged. Under such circumstances, I do not find it prudent, or fair to the Petitioner, to place additional obstacles in the path of the matter's final determination.

In order to guide the parties through the damages phase of the action, a separate damages order will issue.

Pursuant to Vaccine Rule 28.1(a), the Clerk's Office is instructed to deliver this decision to the judge assigned to this case.[13] In the absence of a motion for review, the Clerk's Office is instructed to enter judgment in accord with this decision.

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[12] The Circuit panel took particular umbrage at my observation in the Entitlement Decision that Ms. Sharpe's inability to prove her case (in my initial estimation, of course) did not mean that scientific advancements and discoveries might *in future cases* inure to the benefit of petitioners with similar claims. Entitlement Decision at *40. The Circuit deemed this observation to be akin to requiring scientific certainty, and thus evidence of my misapplication of the legal standard governing causation theories in the Program. Federal Circuit Decision at 1078 ("[t]he Special Master should not have been concerned with what "future research" may show but rather with the research presented in the record"). But this interpretation is facially contrary to my recitation of the legal standard, which readily acknowledges that certainty is not required to prevail. *See, e.g.*, Entitlement Decision at *23 ("[p]etitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory"). Moreover, my reference to scientific advancement, and its bearing on the case, was far more anodyne than the Circuit's decision suggests. I intended only to note that a determination that *one* petitioner has not met his preponderant burden (because of an absence of sufficient *preponderant* evidence at that moment in time) does not mean that a later petitioner—armed with more reliable science or medical evidence, whatever the form it comes in, arising from new advancements in understanding of immunology or the injury at issue—might succeed where the first failed. This is wholly consistent with the fact in the Program that some claimants succeed where others fail (and vice-versa) despite overlapping factual circumstances—and that medical science is always making new discoveries about the impact of vaccines on the human body that can later prove helpful in deciding these cases.

[13] The filing date of this Ruling on Remand is admittedly beyond the 90 days set by the Vaccine Rules for a special master to act on a remanded matter, if only by three days (since the action was formally remanded to me on November

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

16, 2020—meaning acting on remand should have occurred on or before February 16, 2021). *See* Vaccine Rule 28(b). However, the Court of Federal Claims has previously observed that "the Vaccine Act does not identify any consequences for a special master's failure to complete the task directed by the court on review within the statutory ninety-day remand period." *Greene v. Sec'y of Health & Human Servs.,* No. 11-631V, slip. op., at 3 (Fed. Cl. May 30, 2018). In addition, even if this ruling had been issued within that 90-day timeframe, the case's *final* disposition would still remain for a later date, since the parties must now undergo the meticulous process of determining damages in a case involving a plainly-catastrophic injury—and that process will surely take far longer than 90 days. As a result, delay in issuance of my ruling prejudices neither party.